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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/780,152 | 02/17/2004 | Andreas Hefel | RBL0109 | 1277 |

832 7590 12/22/2008

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| EXAMINER | |
|---|---|
| MAEWALL, SNIGDHA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1612 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 12/22/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/780,152 | HEFEL, ANDREAS | |
| | Examiner | Art Unit | |
| | Snigdha Maewall | 1612 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *21-33* is/are pending in the application.

4a) Of the above claim(s) *1-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Summary*

1. Receipt of Applicant's Arguments/Remarks and amended claims filed on 10/23/08 is acknowledged.

Claims 1-20 remain cancelled in this Application.

Claims 21, 24, 30 and 33 have been amended.

Accordingly, claims **21-33** are under prosecution.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 21-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The following claims are very broad:

*Claim 21 (Currently amended): a process for providing a human or animal with at least two active substances and providing an* ***unsubstituted polysaccharide****"*

*Claim 22 and 33 (Previously presented): The process of Claim 21, wherein the polysaccharide comprises at least one polysaccharide selected from the group consisting of galactomannans and glucomannans.*

*Vas-Cath Inc. V. Mahurkar*, *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111, (Fed. Cir. 1991), states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (p. 1117). A review of the language of the claims 24 and 25 indicate that these claims are drawn to a genus, i.e., a "polysaccharide and galactomannan and glucomannons.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states, "An adequate

written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Limitations from the specification cannot be read into the claims and the claims must be given their broadest reasonable interpretation (see MPEP 2111). During examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004). In light of the foregoing, the term "an unsaturated polysaccharide , galctomannan and glucomannon reads on any species that falls under the genus.

*(Prior art WO 99/06023 discloses that the term "galactomannan" refers to polysaccharides derived the natural gums or similar natural or synthetic gums containing mannose or galactose moieties, or both groups, as the main structural components. Preferred galactomannans of the present invention are made up of linear chains of (1-4)-.beta.-D-mannopyranosyl units with .alpha.-D-galactopyranosyl units attached by (1-6) linkages. With the preferred galactomannans, the ratio of D-galactose to D-mannose varies, but generally will be from about 1:2 to 1:4. Galactomannans having a D-galactose:D-mannose ratio of about 1:2 are most preferred. Additionally, other chemically modified variations of the polysaccharides are also included in the "galactomannan" definition. For example, hydroxyethyl, hydroxypropyl and carboxymethylhydroxypropyl substitutions may be made to the galactomannans of the present invention. Non-ionic variations to the galactomannans, such as those containing alkoxy and alkyl (C1-C6) groups are particularly preferred when a soft gel is desired (e.g., hydroxylpropyl substitutions). Substitutions in the non-cis hydroxyl positions are most preferred. An example of non-ionic substitution of a galactomannan of the present invention is hydroxypropyl guar, with a molar substitution of about 0.4. Anionic substitutions may also be made to the galactomannans. Anionic substitution is particularly preferred when strongly responsive gels are desired).*

Applicants have not shown possession of each and every unsubstituted polysaccharide. In the absence of specific polysaccharide/galactomannan and glucomannan, the claim as recited lacks written description requirements. The disclosure specifies only single polysaccharide which is **guar,** however no other representative examples have been set forth in the disclosure.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claims encompass numerous species that are not further described. While "examples explicitly covering the full scope of the claim language" typically will not be required, a sufficient number of representative species must be included to "demonstrate that the patentee possessed the full scope of the [claimed] invention." Lizardtech v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005).

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is a polysaccharide or galactomannan or glucomannan due to which the release rate will be delayed. The delayed release profile claimed is due to polysaccharide, however it is a well known fact that all polysaccharides have their own structural characteristics which is associated with their functional characteristics. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features (see, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 927, 69 USPQ2d 1886, 1895 (Fed. Cir. 2004); accord Ex Parte Kubin, 2007-0819, BPAI 31 May 2007, opinion at p. 16, paragraph 1). The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites the limitation "below physiological levels that are adverse to the human or animal". The phrase is indefinite and unclear.
It is unclear as to which levels are adverse. Specific recitation of levels is requested. Claim 27 recites the limitation "gradual". Gradual is a relative term which renders the claim indefinite. Examiner suggests reciting specific release rate. Claim 30 recites the limitation "do not does exceed physiological levels" which makes the claim indefinite. It is not clear which physiological needs is the applicant referring to. The limitation "sustained supply is a relative term which makes the claim indefinite in claim 31. Examiner suggests reciting specific release rate.

**Response to Arguments**

6. Applicant argues that the terms gradual and sustained are well known in the art, thus these terms should be sufficiently clear.

The rejection is maintained with respect to the phrases gradual and sustained since no specific release rate is defined. It should be noted that claim 21 does not recite any specific polysaccharide, since gradual is a relative term, the claims lack specificity. (USPTO personnel are to give claims their broadest reasonable interpretation in light of

the supporting disclosure. In re Morris, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim should not be read into the claim. E-Pass Techs., Inc. v. 3Com Corp., 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (claims must be interpreted "in view of the specification" without importing limitations from the specification into the claims unnecessarily). In re Prater, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See also In re Zletz, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2257358 A.

GB 2257358 A discloses a composition comprising vitamins, enzymes, coenzymes, minerals, trace elements and/or microorganisms that are embedded, separately with regard to function, in carrier substances with formation of protective films against harmful effects so that, with sufficient moisture absorption, in vivo and in vitro biocatalytic processes can be initiated and controlled. Suitable protective substances

are preferably sodium salts and potassium salts of silicic acid and nonionic polysaccharides, in particular from the family consisting of the galactomannans (page 2, paragraph 2 and **claim 5**). The process of mixing and drying is depicted on page 4, paragraph 4, page 7, paragraph, 1 and in example 2). It is further disclosed that the **granulation** can be influenced by the spraying rate and the enzyme powders are obtained in relatively narrow particle size ranges after drying (page 8, paragraph 1). It is to be noted that claims 25-28 provide the functional limitations once the active substance is introduced into human or animal, since the claimed compound is similar to the compound disclosed in the prior art, the functional limitations are considered associated to the process. Based on the teachings of the prior art, it would have been obvious to one of ordinary skilled in the art at the time of the instant invention to formulate a process of providing a human or animal a composition comprising two active ingredients with no antagonistic interactions between the two. A skilled artisan would thus have arrived to claimed invention of providing a human or animal with at least two active substances comprising polysaccharide in the form of granules with a reasonable expectation of success.

***Response to Arguments***

9. Applicant's arguments filed 09/19/2007 have been fully considered but they are not persuasive. Applicant argues that the prior art has examples limited to the industrial processes and embedding of active ingredient in the reference is designed to protect the active from pressure and temperature. The instant claims are directed to

administering first active and second active to human or animal use and the instant administration comprises distinct active not mixture. Applicant's arguments are not persuasive.

Gabara teaches a composition comprising vitamins, enzymes that are embedded separately with regard to function, hence they read on being distinct. Polysaccharides such as galactomannans are disclosed on page 2, paragraph 2. Secondly, the reference is not limited to preferred examples; the reference is considered as a whole during prosecution and as discussed in the rejection above application of the product made by the known process is an intended use. The process of the instant claims is obvious over the prior art.

Applicant argues that prior art does not disclose the particle size claimed. Applicants arguments are not persuasive since the prior art distinctly teaches that **granulation** can be influenced by the spraying rate and the enzyme powders are obtained in relatively narrow particle size ranges after drying (page 8, paragraph 1). The rejection is maintained.

**10.** Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore /

Primary Examiner, Art Unit 1612